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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,440	KUHAR ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-15 are pending. Claims 1-15 are under consideration in the instant office action.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119 (a)-(d).

Information Disclosure Statement

The information disclosure statement (IDSs) submitted on 06/16/06 is noted and the submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the references.

Claim Objection

Claim13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should recite in the alternative. See MPEP § 608.01(n). Accordingly, the claim 13 not been further treated on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 provides for the use of the pharmaceutical formulation of claim 13 for the preparation of a medicament for the treatment of benign prostatic hyperplasia, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Chen et al. (US Patent 6602522).

Instant claim1 recites a controlled release pharmaceutical formulation comprising a pellet core and a low dose active substance. Instant claim 2 recites a controlled release pharmaceutical formulation comprising at least one insoluble permeable polymer, a surfactant, and optionally other excipients. Instant claim 3 recites a formulation according to claim 2 wherein the polymer is an acrylic alkylcellulose, hydroxyalkylcellulose or combinations thereof. Instant claim 4 recites the formulation according to claim 3 wherein the polymer is an ethylacrylate/methylmethacrylate copolymer in a ratio of 2:1 which is optionally a 30% aqueous dispersion. Instant claim 5 recites the formulation of claim 1 where in the diameter of the core is about 0.5-1.25. Instant claim 6 recites the formulation of claim 1 wherein the core is coated with a gastroresistant and/or release controlling coating. Instant claim 7 recites the formulation of claim 6 wherein the coating is 5-10% by weight relative to the core. Instant claim 8 recites the formulation according to claim 7 wherein the coating is 5-8% by weight relative to the coating. Instant claim 9 recites the formulation according to claim 6 wherein the coating comprises a polymer soluble above 5.5 and a polymer soluble independent of pH. Instant claim 10 recites the formulation according to claim 9 wherein the polymers are an anionic copolymer of methacrylic acid and ethylacrylate and a ethylacrylate and methylmethacrylate copolymer, respectively. Instant claim 11 recites the formulation of claim 1 wherein the pellets are formed into capsules, sachets, or tablets. Instant claim 12 recites the formulation of claim 1 wherein the cores are prepared by extrusion or spheronization. Instant claim 14 recites a process for preparing the formulation of claim 1 comprising blending ingredients, granulation, extrusion, spheronization drying and optionally coating.

Chen et al. discloses a pharmaceutical composition comprising a core and a coating layer (abstract). The core contains a therapeutic active ingredient, a surface active agent, a filler, an alkaline agent, and a binder (column 2, lines 10-20). The binder can be a water-insoluble polymer such as a polymethacrylic acid copolymer such as Eudragit NE30D (ethlacrylate/jmethylmehacrylate 2:1) which is available as a 30% aqueous dispersion (column 3, line 19-26). The enteric coating resists acid up to about pH 5 or higher (column 3, lines48-50). The examiner notes that the pH 5 disclosed by Chen et al. is about pH 5.5 in instant claim 9. Moreover, Chen et al. teaches the same polymers as specified in instant claims 9 and 10 and the pH solubility of the polymer is an inherent property of the polymers. The coating, therefore, controls the release of the active agent. In examples 1-5, the tables are either 0.2812" or 0.3125" which the examiner calculates corresponds to 0.714 cm or 0.794 cm respectively (column 5, line 32; column 6, line 27; column 7, line 30; column 8, lines 24 and 64). The coating preferably comprises a combination of polymers including, for example Eudragit L30-55 (methacrylc acid and ethylacrylate) and Eudragit NE30D (ethlacrylate/methylmehacrylate 2:1). The active ingredient and other ingredients for the core are combined, granulated, dried, formed into tablets, and coated (column 4, lines 20-33). According to the examiners calculations, the coating of example 1 is 7.7% of the tablet (column 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US Patent 6602522) as applied to claims 1-12 and 14 above, and further in view of Platteeuw (US Patent No. 7018658).

Applicant Claims

The claimed subject matter of instant claims 1-12 are set forth above. Instant claim 13 recites the formulation of the preceding claims wherein the substance is tamsulosin or salt thereof. Instant claim 15 recites use of the pharmaceutical formulation

of claim 13 for the preparation of a medicament for the treatment of benign prostatic hyperplasia.

Note: The examiner for prior art rejection purpose interpreted instant claim 15 as a method of making the medicament.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Chen et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Chen et al. do not teach the inclusion of tamsulosin as the active ingredient. These deficiencies are cured by the teachings of Platteeuw.

Platteeuw teaches a controlled release formulation of tamsulosin in a pellet core (abstract). Platteeuw also teaches process of preparing the controlled release formulation of tamsulosin comprising granulating a mixture of tamsulosin hydrochloride, microcrystalline cellulose, acrylic polymer, water and optionally auxiliary ingredients to form wet pellet cores, drying the wet pellet cores to a residual amount of water of 2-10%, sieving the dried pellet cores to obtain a fraction within the size range of 0.3-0.9 mm, coating the sieved dried pellet cores with a coating composition that comprises an acid-resistant water soluble acrylic polymer, and drying the coated pellets, wherein the coating step is sufficient to provide the dried coated pellets with 2.5-15 mass % of the coating composition, calculated on the dry pellet core basis (column 2, lines 41-52 and column 5, lines 34-53).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to use tamsulosin as the active ingredient because Platteeuw teach a controlled release formulation of tamsulosin. An ordinary skilled artisan would have been motivated to use tamsulosin as the active ingredient because Platteeuw teach that there is a need of longer extended release dosage forms for tamsulosin (column 2, lines 1-15). An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because controlled release formulations are common and well known in the art for a variety of different active ingredients.

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-15 are pending. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

01/29/09

/PORFIRIO NAZARIO GONZALEZ/
Primary Examiner, Art Unit 1621